DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

September 14, 2001

Our Submission Tracking Number: BL 102692/1009
Our Reference Number: 98-0872

Ralph Eatz
Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625

Dear Mr. Eatz:

Your Biologics License Application for Anti-B (Murine Monoclonal) derived from the LB-2 cell line, for production into Blood Grouping Reagent under a shared manufacturing agreement with [redacted] is approved effective this date.

Under this license you are hereby authorized to introduce or deliver for introduction into interstate commerce Anti-B (Murine Monoclonal) manufactured from the LB-2 cell line at Immucor, Inc. under U.S. License No. 0886. Changes to the product, production process, location of production process, equipment, facilities, or responsible personnel are required to be reported to FDA as specified in Title 21 Code of Federal Regulations (CFR) Section 601.12. In addition, any significant decrease in the potency or other change in this product should be reported promptly to the Center for Biologics Evaluation and Research.

The dating period for this product shall be 2 years from the date of manufacture when stored at 1-10° C. The date of manufacture shall be defined as the date of the last valid potency test.

You are requested to submit samples of each future lot of this product together with protocols showing results of all applicable tests. No lots of product shall be distributed until notification of release is received from the Director, Center for Biologics Evaluation and Research (CBER).

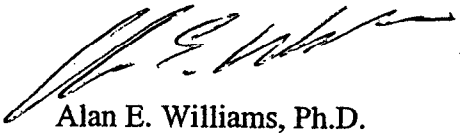
All adverse events must be documented and submitted according to 21 CFR 800. Required reports should be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, Maryland 20847-3002.

Please submit three (3) copies of final printed labeling at the time of use accompanied by Transmittal of Labels and Circulars Form FDA 2567 with completed implementation information. In addition, you may wish to submit your proposed introductory advertising and promotional campaign. If so, please submit three (3) copies of the proposed material in draft form with Part I of the FDA Form 2567/2253 to CBER, Advertising and Promotional Labeling Branch (APLB), HFM-602, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Promotional claims should be consistent with and not contrary to the approved labeling. No comparative claims or claims of superiority over other similar products should be made

unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2567/2253 to APLS. Please include copies of the approved labeling with your proposed or final copy of advertising and promotional materials submitted to CBER.

It is recommended that a copy of this letter be available for review at the time of FDA inspections.

Sincerely yours,



Alan E. Williams, Ph.D.
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Office of Blood Research and Review
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